



DIVISION OF HEALTH CARE FINANCING

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Jim Doyle
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State of Wisconsin

Department of Health and Family Services

August 2, 2004

Dear CSP/Case Manager:

You are being contacted because you or your agency provides case management services for Medicaid recipients on brand name clozapine (Clozaril®). Attached to this letter are the names of your clients who are on Medicaid and who have filled a prescription for brand name Clozaril® in the past two months.

Effective September 1, 2004, Wisconsin Medicaid, BadgerCare and SeniorCare will require prior authorization (PA) for brand medically necessary drugs, including Clozaril®. This letter describes the new policy and what you need to do to ensure the safe transition for Medicaid patients currently taking brand name Clozaril®. It also describes the process for seeking PA under the new policy.

Medicaid Patients on Clozaril®

- 1) Counsel your patients on brand name Clozaril® about switching to the generic.
- 2) Work with the prescriber to issue a new prescription order to the pharmacy for generic clozapine if the patient can be switched to the generic.
- 3) Work with the prescriber to contact the pharmacy to begin PA if the patient must remain on brand name Clozaril®.

What do prescribers need to do before September 1, 2004?

- **Counsel your patient taking brand name Clozaril®.** Help your patient understand what the change is and that most patients can be switched without adverse effects.
- **Authorize the change to generic clozapine.** Medicaid patients taking brand name Clozaril® will need a new prescription for generic clozapine. The prescriber should contact the pharmacy prior to September 1, 2004, with a new prescription order.

- **Complete the PA for brand name Clozaril®.** If the patient should remain on brand name Clozaril®, work with the prescriber to contact the pharmacy to begin the PA process
- **Start new patients on a generic formulation.** Any new patient will be expected to start on generic clozapine rather than brand Clozaril®. Any patient who is admitted to the hospital where generic clozapine is used will be expected to remain on generic clozapine after discharge, unless it is clinically demonstrated that the person had a therapeutic failure, or an adverse or allergic reaction to generic clozapine.

What should CSP/Case Managers do?

- **Counsel Patients.** It is important that you, as the patient's case manager, counsel patients about the upcoming change in their medication. Misunderstandings can be avoided and acceptance improved if patients are given factual information and have an opportunity to have their questions answered. A copy of a brochure that can be used with patients to help explain the change is enclosed. Additional copies of the brochure are available on the Medicaid web site at: dhfs.wisconsin.gov/medicaid

Some patients may react to the pill being “different.” This is not a pharmacological response, but can still be a stress that can cause clinical problems, including a change in the patient's comfort to take the “new medication,” even though it is really the same medication he or she has been on. Almost always, reassurance that this is the same medication and comfort on the part of the clinical staff can help the patient get through this period of potential difficulty. At times, a dose adjustment or additional monitoring may be needed. In rare cases, this may cause such problems that the patient needs to return to brand name Clozaril®. If the patient needs to return to brand name Clozaril®, the prescriber should follow the instructions in the Wisconsin Medicaid and BadgerCare update to obtain PA.

- **Monitoring.** Clozaril® and generic clozapine are different from most other medications due to the requirement for a lab monitoring system. Each pharmaceutical company manufacturing clozapine has a monitoring system in place. If the prescriber makes arrangements with the pharmacy in advance to switch the patient's prescription order to generic clozapine, the pharmacy can arrange the switch seamlessly to the new monitoring system. This will reduce the need for patients to wait for their prescription while the pharmacist makes the necessary calls to switch to the new monitoring system.

Since the brand and generic medications are chemically identical, there is generally no need to titrate, adjust dose, or to obtain serum levels. There are potential differences in dissolution rate from the use of different binders, and in some rare cases there have been reports that dose adjustment has been necessary.

Clozapine levels typically change both over time and day to day, depending on many clinical factors. For example, changes in smoking and eating patterns can influence levels much more than a change that might result from switching from brand to generic.

It is possible that some patients may be very sensitive to small changes in serum levels. Some dose adjustment may be necessary after the switch from brand to generic medication. These patients are sensitive to minor changes in medication use and other variables and have historically required closer monitoring and more frequent medication adjustments.

Some physicians prefer to take pre-and post-switch clozapine levels. Although this is unnecessary for most patients, Medicaid will pay for these serum levels, if you believe they are clinically appropriate.

What criteria will be used to determine who can stay on brand name Clozaril®?

PA will be approved to continue on brand name Clozaril® only when the patient has:

- An adverse reaction to the generic drug(s).
- An allergic reaction to the generic drug(s).
- An actual or anticipated therapeutic failure of the generic drug(s).

What information is available to assist CSPs/case managers?

- **Brochure.** The attached brochure on “Clozapine and Clozaril®.” was developed to provide information to Medicaid recipients on substituting generic clozapine for brand Clozaril®. Additional copies of this brochure can be downloaded from the Medicaid web site at: dhfs.wisconsin.gov/medicaid
- **Medicaid Web Site.** Information is also available on the Medicaid web site at dhfs.wisconsin.gov/medicaid, including:
 - A memorandum to consumers on generic medications
 - Medicaid and BadgerCare Update to Prescribers
 - Medicaid and BadgerCare Update to Pharmacies
- **Conference Call with CSPs/Case Managers.** On Friday, August 13, 2004, from 10 a.m. to 12 p.m., the State Bureau of Mental Health and Substance Abuse will sponsor a statewide telephone discussion on the substitution of generic clozapine for the brand name medication Clozaril®. The purpose of the teleconference is to describe these special provisions and address clinical questions and concerns.

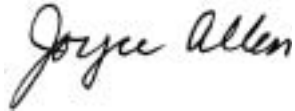
The teleconference will start with a joint presentation by Dr. Ron Diamond, Joyce Allen, Florene Birch, R.N. and Elaine Gundlach, R.N.. Over half of the teleconference will be set aside for questions and answers.

August 2, 2004

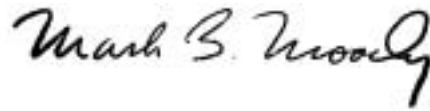
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In order to have a sufficient number of teleconference lines, please contact Bonnie Benson before August 10 at bensobb@dhfs.state.wi.us or (608) 264-7754 to make a reservation for a line for your agency.

Sincerely,



Joyce Bohn Allen
Director
Bureau of Mental Health and Substance Abuse



Mark B. Moody
Administrator
Division of Health Care Financing

JBA:MBM:my
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Attachments